Form No.:CR-D-028

DECLARATION OF CONFORMITY TO COUNCIL REGULATION (EU) 2017/745 CONCERNING MEDICAL DEVICES

MANUFACTURER: Shenzhen Creative Industry Co., Ltd.

Floor 5, BLD 9, Baiwangxin High-Tech Industrial Park,

Songbai Road, Xili Street, Nanshan District,

518110 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

SRN OF the MANUFACTURER: CN-MF-000009430

MEDICAL DEVICE: Blood Pressure Cuff

MODEL: 15020010/15020011/15020013/15020014/15024402/

 $\frac{15023402/15024403/15020022/15020024/15022402/15020030/15020029/15020056/15020034/15020036}{15020030/15020029/15020056/15020034/15020036}$

INTENDED USE: The blood pressure cuffs are indicated for use in manual

measurement and automatic non-invasive blood pressure

monitoring.

CLASSIFICATION - ANNEX VIII: Class I, Rule 1

BASIC UDI-DI: 69419006Cuff35

CONFORMITY ASSESSMENT ROUTE: Annex II+ Annex III

WE, **Shenzhen Creative Industry Co., Ltd.**, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICESMEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL REGULATION (EU) 2017/745 CONCERNING MEDICAL DEVICES; ALL SUPPORTING DOCUMENTATION ARE RETAINED UNDER THE PREMISES OF THE MANUFACTURER. WE ARE EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.

STANDARDS APPLIED:

EN ISO 15223-1:2021	EN ISO 20417:2021	EN ISO 10993-1:2020
EN ISO 10993-5:2009	EN ISO 10993-10:2013	

EC REP

SIGNATURE:

EUROPEAN REPRESENTATIVE: Shanghai International Holding Corp. GmbH (Europe)

Eiffestraβe 80, 20537 Hamburg, Germany

SRN OF the European Representative: DE-AR-00000001

PLACE, DATE OF DECLARATION: Shenzhen, Mar.29, 2022

N-9"

NAME: Zhang Xiang

POSITION: Management Representative

1 of 1 revision date May. 2021